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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,161	03/30/2001	Michael Detmar	MGH 1512 CIP	6294

7590 08/22/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 08/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,161

Applicant(s)

DETMAR, ET AL.

Examiner

Natalie A. Davis

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed 4 June 2002 (Paper No: 7) is acknowledged. Accordingly, claims 8-15 are withdrawn from consideration as being drawn to a non-elected invention and claims 1-7 are under examination.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority Objection - Maintained

1. Objection to applicants claim for domestic priority under 35 U.S.C. 119(e) to provisional application 60/127,221 is maintained. Applicants argue that provisional 60/127,221 discloses a gene therapy construct, which can comprise a slow release matrix with an imbedded gene delivery vehicle and said matrix is analogous to the instant invention. Applicant's arguments have been considered but are not persuasive. The instant application is drawn to a method of treatment comprising implanting a cell-matrix structure with attached cells, which express a gene encoding an anti-angiogenic molecule, but does not disclose a slow release matrix or an imbedded gene delivery vehicle. Accordingly, the scope of the instant application and the provisional application are drawn to two different matrixes, as a cell-matrix structure with attached cells is different from a slow release matrix.

Claim Rejections - 35 USC § 112 1st Withdrawn

2. Rejection of claim 2 under 35 U.S.C.112, first paragraph is withdrawn in view of arguments.

Claim Rejections - 35 USC § 103 Withdrawn

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3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti, et al., 1988 and 5,759,830 in view of Locopo, et al., (1998) and Streit, et al., (1999) is withdrawn in view of arguments.

New Rejection-Oath/Declaration

4. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth. The oath/declaration does not acknowledge the instant application as a continuation in part of 09/536,087, filed 03/24/2000 and a continuation in part of application 09/770339, filed 01/26/2001. A new oath/declaration is required in the body of which the present application should be identified by application number and filing date.

New Rejection-Specification

5. The specification must be amended to indicate that the instant application is continuation in part of 09/536,087, filed 03/24/2000 and a continuation in part of application 09/770339, filed 01/26/2001 and claim status of the nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

New Claim Rejections - 35 USC § 112

6. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the anti-angiogenic molecule thrombospondin-2 (TSP-2), does not reasonably provide enablement for thombomodulin or any anti-angiogenic molecule excluding TSP-2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the

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invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are drawn to a method of treatment comprising implanting a cell-matrix structure with attached cells, which express a gene encoding an anti-angiogenic molecule. Claim 6 is specifically drawn to thrombomodulin as the anti-angiogenic molecule. The specification discloses a method of treatment comprising implanting a cell-matrix structure with attached cells, which express a gene encoding TSP-2, but not thrombomodulin or any other molecule. There is no teaching or exemplification in the specification indicating that thrombomodulin or any molecule other than TSP-2 may be used in the method as claimed. Accordingly, the specification only supports thrombospondin-2 as anti-angiogenic molecule that may be used in the method as claimed. In view of the following, the claims are drawn to matter not supported by the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
August 19, 2002


SHEELA HUFF
PRIMARY EXAMINER